IN THE UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

United States of America, Plaintiff, *ex rel.* Leanne Houston, Relator, v. Medtronic, Inc., Defendant.	)	Civ. No. 2:20-cv-3367-BHH **AMENDED COMPLAINT** **(JURY TRIAL DEMANDED)**

Relator Leanne Houston files this Amended Complaint pursuant to the False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq.*, to recover monies illegally obtained by Defendant Medtronic, Inc., from federal health insurance programs through the fraudulent sale of defective surgical staplers, and for treble damages and civil penalties arising from those fraudulent sales, and for all damages allowed by law for Medtronic's termination of her employment in retaliation for her efforts to prevent Medtronic's fraudulent conduct, and alleges as follows:

INTRODUCTION

1. At the end of April 2018, Relator Leanne Houston was Medtronic's top sales representative in the entire country. For her record job performance, she received a glowing performance review and was promoted (again) in July 2018.

2. In the preceding twelve months, Ms. Houston's biggest responsibility had been the "conversion" of McLeod Health Inc. (McLeod), a hospital network in northeastern South Carolina. A "conversion" was a sales campaign to persuade a hospital network to contract to use only Medtronic's surgical products and to terminate its relationships with competing suppliers.

Medtronic "converts" hospital networks to use its products exclusively by aggressive marketing campaigns aimed at non-physician decisionmakers at the hospital. To persuade these decisionmakers, Medtronic promises to undercut competitor prices significantly, which requires cutting costs somewhere, which is why Medtronic's surgical staplers, among other devices, are of notoriously poor quality and comprise 95% of all staplers recalled from the market.

3. The poor quality of Medtronic's surgical staplers is well known and has been the subject of many lawsuits and regulatory actions. What was not well known and what Ms. Houston relates as an original source, based on insider information, is that in late August 2018, she began reporting concerns raised by McLeod surgeons that Medtronic's GIA80 surgical staplers were defective and were causing serious harm to patients. Medtronic responded by concealing the defect to avoid a recall, which it did by falsely reporting the adverse incidents to the U.S. Food and Drug Administration (FDA) and by telling non-surgeon executives at McLeod that the issue was user error, when it knew that was not the case. Ms. Houston however was not willing to conceal the defect to help preserve the "conversion," so in October 2018 she was suspended and in early December 2018 she was informed she would be terminated for "incompetence." Her job performance, however, was so excellent that on the day she was terminated she was still the top sales representative in her region—even with the extra three months of her suspension, no one could catch up with her.

4. Medtronic's fraudulent concealment of the defect in its GIA80 staplers caused serious injury to many patients at McLeod, and, doubtlessly, other hospital networks. It also caused the Government to pay for services made worthless by the defective surgical staplers, which it would not have paid for had Medtronic not fraudulently concealed the truth. And Medtronic's retaliation against Ms. Houston for her statutorily protected whistleblowing to protect patients

unable to protect themselves as they lie unconscious in an operating room left Ms. Houston unemployed in her 50s with no ability to obtain employment in the industry she had worked in for thirty years.

JURISDICTION AND VENUE

5. This action arises under the FCA. The Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331 & 1345 and 31 U.S.C. § 3730(b) & 3732(a).

6. The Court has personal jurisdiction over Medtronic pursuant to 31 U.S.C. § 3732(a) because Medtronic transacts business in this District and numerous acts prohibited by federal law occurred in this District.

7. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a). Further, many prohibited acts complained of herein occurred in this District, and witnesses and documents regarding those prohibited acts are located within this District.

8. Ms. Houston's claims and this Amended Complaint are not based upon the prior public disclosure of allegations or transactions in a criminal, civil, or administrative hearing in which the Government or its agent is a party; in a congressional, Government Accountability Office, or other federal report, hearing, audit, or investigation; or from news media, as enumerated by 31 U.S.C. § 3730(e)(4)(A). To the extent there has been a public disclosure unknown to Ms. Houston, she is the "original source", and the public disclosure is a result of Ms. Houston providing this information to the United States. *See* 31 U.S.C. § 3730(e)(4)(B).

THE PARTIES

9. Relator Leanne Houston is a citizen of the United States. She was employed by Medtronic and has inside knowledge that is independent of and materially adds to publicly disclosed information regarding Medtronic's business related to medical devices. In 2018, Medtronic employed her as a sales executive. At that time, she had 28 years' experience in medical

device sales. In late April 2018, she was honored as Medtronic's top performing sales executive in the entire country. She received a promotion in July 2018. Beginning in August 2018, she began repeatedly speaking out regarding device concerns and patient safety. In December 2018, she was informed she would be terminated for "incompetence, and she was terminated in January 2019.

10. Ms. Houston became aware of Medtronic's fraud alleged herein through her position as an original source and insider within Medtronic. Ms. Houston has commenced this *qui tam* action against Medtronic on behalf of the United States based upon her personal experiences and insider information.

11. Ms. Houston has provided the United States Attorney a full disclosure of substantially all material facts supporting this Complaint, as required by 31 U.S.C. § 3730(b)(2).

12. Defendant Medtronic, Inc., is a corporation incorporated under the laws of the State of Minnesota with its principal place of business in Minnesota. Medtronic caused the Government to allow or pay false claims for procedures by knowingly selling defective and unreliable surgical staplers for use in hospitals and medical centers that receive reimbursement from Medicaid, Medicare, and other government insurance programs. Defendants knew that doing so was unsafe, fraudulent, and illegal.

STATUTORY AND REGULATORY AUTHORITY APPLICABLE TO THIS ACTION

I. Federal Health Insurance Programs

13. The federal government is a principal purchaser of surgical procedures using Medtronic staplers through several federal health insurance programs, including, but not limited to Medicare, Medicaid, and the Federal Employee Health Benefits Program (FEHBP) (collectively, "Government Health Insurance Programs").

A. Medicare

14. Medicare is a federal health program primarily benefiting the elderly that Congress created in 1965 when it adopted Title XVIII of the Social Security Act.

15. Medicare is administered by the Centers for Medicare and Medicaid Services (CMS) within the U.S. Department of Health and Human Services (HHS).

16. There are four parts to Medicare: Medicare Part A (hospital insurance), Medicare Part B (medical insurance), Medicare Part C (Medicare Advantage), and Medicare Part D (prescription drug benefit).

17. Medicare Part A pays for inpatient hospital care for beneficiaries. *See* 42 U.S.C. §§ 1395e– 1395i-5. Procedures using the gastrointestinal surgical staplers at issue in this action are performed in an inpatient setting. Medicare Part C is an optional plan that combines coverage offered under Parts A with other coverages under Medicare Advantage plans administered by private insurance companies.

B. Medicaid

18. In 1965, Congress added Title XIX to the Social Security Act and created Medicaid.

19. Medicaid is a public assistance program providing payment of medical expenses to low-income patients.

20. Medicaid is funded jointly by the federal government and state governments.

21. Medicaid's coverage is modeled on Medicare's coverage and the requirement that only reasonable and necessary costs are reimbursable.

C. FEHBP

22. FEHBP provides health insurance coverage for more than 8 million federal employees, retirees, and dependents through a collection of individual health care plans, including the BlueCross and BlueShield Association, Government Employees Hospital Association, and

Rural Carrier Benefit Plan. FEHBP plans are managed by the Office of Personnel Management and are funded with federal tax funds.

II. The False Claims Act

23. The FCA provides that any person who knowingly presents or causes another to present a false or fraudulent claim for payment or approval is liable for a civil penalty of up to $27,894 for each such claim, plus three times the amount of the damages sustained by the government. 31 U.S.C. § 3729(a)(1)(A) & (B).[1]

24. Liability attaches to anyone who (1) causes to be presented for payment or approval by the United States (2) a false or fraudulent claim, (3) knowing the claim was false or fraudulent. *See* 31 U.S.C. § 3729(b)(2).

25. When a supplier knowingly provides worthless product of no medical value to obtain government reimbursement, the claim for reimbursement is factually false and actionable under the FCA. *See, e.g.*, *United States ex rel. Jackson v. DePaul Health Sys.*, 454 F. Supp. 3d 481, 494 (E.D. Pa. 2020), *United States ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 158 (E.D. Pa. 2012).

26. Failure to comply with a regulation that informs the quality of the service at issue can be the basis for a claim under a worthless services theory because seriously deficient services are akin to a product that does not work. *Jackson*, 454 F. Supp. 3d at 495 (citing *United States ex rel. Scharber v. Golden Gate Nat'l Senior Care LLC*, 135 F. Supp. 3d 944, 965 (D. Minn. 2015)).

[1] The maximum civil penalty during the time Ms. Houston witnessed Medtronic's fraud was $22,363 per transaction.

III. Medical Device Regulations

27. The FDA is the federal agency responsible for protecting the health and safety of the public by enforcing the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, and assuring (among other things) that medical devices are safe and effective for their intended uses. Pursuant to such responsibility, FDA publishes and administers regulations relating to the approval, manufacture, and distribution of medical devices.

28. The required FDA approval to market a medical device is subject to the general controls provisions of the FDCA, which include requirements good manufacturing practice and prohibitions against adulteration. 21 U.S.C. § 360c(a)(1)(A)(i).

A. Adverse Event Reporting Requirements

29. During Ms. Houston's employment at Medtronic, surgical staplers for internal use were classified as Class I medical devices (*see* 21 U.S.C. § 360c), regulated by, *inter alia*, 21 U.S.C. § 360i and FDA's Medical Device Reporting (MDR) regulations. *See* 21 C.F.R. §§ 803 *et seq.*

30. Both 21 U.S.C. § 361i the MDR regulations classify two types of adverse events that must be reported by device manufacturers: (a) deaths and serious injuries that a device has or may have caused or contributed to and (b) certain device malfunctions. *See* 21 C.F.R. § 803.1; *see also* 21 C.F.R. §§ 803.50–803.56 (setting forth timing and content of required reports).

31. The regulations explain that the various "reports help [the FDA] to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use." 21 C.F.R. § 803.1.

32. An "MDR reportable event" is defined by the regulations as

> An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:

(i) May have caused or contributed to a death or serious injury, or

(ii) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

21 C.F.R. § 803.3(o)(2).

33. A "malfunction" is defined by 21 C.F.R. § 803.3(k) as

the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in § 801.4 of this chapter.

34. "[B]ecome aware" for a manufacturer means

when any of [the manufacturer's] employees becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because [FDA] had requested reports in accordance with § 803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

21 C.F.R. § 803.3(b).

35. Thus, manufacturers must report adverse events associated with a medical device to the FDA within 30 days after the manufacturer becomes aware that a device may have caused or contributed to serious injury, or that a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction was to recur. *See also* 21 C.F.R. § 803.50. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for investigating each adverse event and must evaluate the cause of the adverse event. 21 C.F.R. § 803.52.

36. Manufacturers must also describe in every individual adverse event report whether remedial action was taken regarding the adverse event, and whether the remedial action was reported to the FDA as a removal or correction of the device. 21 C.F.R. § 803.50(b).

37. Manufacturers must report to the FDA within five business days after becoming aware that an MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. 21 C.F.R. § 803.53.

38. Similarly, device manufacturers must report promptly to the FDA any device corrections and removals and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of federal law caused by the device that may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed that are subject to correction or removal and provide a copy of all communications regarding the correction or removal. 21 C.F.R. § 806.10.

B. <u>Current Good Manufacturing Practice</u>

39. FDA approval is also subject to compliance with current good manufacturing practice (cGMP).

40. Pursuant to 21 U.S.C. § 360j(f), device manufacturers must comply with cGMP as specified by regulations codified at 21 C.F.R. §§ 820 *et seq.*

41. This requires "manufacturers [to] develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing

for that specific device." "Quality System (QS) Regulation/Medical Device Good Manufacturing Practices, FDA website. Manufacturers must develop a Quality System (QS) compliant with regulations that "will result in devices that are safe and effective, and to establish methods and procedures to design, produce, distribute, etc. devices that meet the quality system requirements." *Id.* It is the responsibility of a manufacturer's executive management to establish and maintain a QS. 21 C.F.R. § 820.20.

42. In addition, pursuant to 21 C.F.R. § 820.100, manufacturers must "establish and maintain procedures for implementing corrective and preventive action." The corrective and preventative action (CAPA) procedures must be documented and must include procedures for:

> (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;
>
> (2) Investigating the cause of nonconformities relating to product, processes, and the quality system;
>
> (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
>
> (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;
>
> (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
>
> (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
>
> (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

21 C.F.R. § 820.100(a) & (b).

C. Adulterated and Misbranded Devices

43. Title 21 U.S.C. § 331(a) prohibits manufacturers from "introduc[ing] . . . into interstate commerce [] any . . . device . . . that is . . . adulterated or misbranded."

44. A device is deemed adulterated if, inter alia, its manufacture fails to meet performance standards or specifications or current good manufacturing practice (cGMP). 21 U.S.C. §§ 351(e), (h); *United States ex rel. Wallace v. Exactech, Inc.*, No. 2:18-CV-01010-LSC, 2020 WL 4500493, at *12 (N.D. Ala. Aug. 5, 2020) ("[a] device that does not comply with cGMPs is considered 'adulterated' and cannot be sold in the United States") (citing 21 U.S.C. § 331).

FACTUAL ALLEGATIONS

45. Medtronic fraudulently concealed dangerous defects in surgical staplers, which caused the presentment of claims to Government Health Insurance Programs for procedures that were worthless because they caused injury to Medicare and Medicaid beneficiaries.

I. Leanne Houston, Medtronic's top-performing sales executive, led the successful "conversion" of McLeod Health.

46. Leanne Houston finished graduate school in 1989, with a master's degree in business administration earned after her bachelor's degree in marketing.

47. She began working in medical sales in 1990 for Procter & Gamble. She held various sales roles with Boston Scientific and Covidien and was hired as a sales executive at Covidien in December 2013, shortly before Medtronic acquired it.

48. Ms. Houston finished in the top 20% of her Medtronic trainee class and won a national sales contest in her first two years. She was promoted to combined sales executive in 2015.

49. Relator's sales territory included much of eastern South Carolina. In November 2017, she became responsible for the "conversion" of McLeod. A "conversion" was a sales

campaign to persuade a hospital network to contract to use only Medtronic's surgical products and to terminate its relationships with competing suppliers.

50. On November 17, 2017, Ms. Houston took McLeod decisionmakers on a "VIP" trip to Medtronic's manufacturing facility in North Haven, Connecticut. The group was comprised only of procurement office personnel and nurses. No surgeons or physicians of any sort were included. What benefit they could receive from visiting a surgical device manufacturing facility is unclear. What is clear, based on receipts retained by Ms. Houston, is that Medtronic spent thousands of dollars providing them with beer, wine, cosmopolitans, margaritas, tequila shots, and fireball shots. At the conclusion of the evening, when the decisionmakers were happily drunk, Ms. Houston texted her supervisor that the trip was a success and that the "conversion is a go."

51. Of course, the conversion's success was not only because Medtronic provided a drunken bender for non-physician bean-counters. The McLeod conversion led by Ms. Houston succeeded because it promised them $1.2 million in cost savings.

52. After the conversion, McLeod surgeons used Medtronic surgical staplers without issue from February 2018 to August 2018 without issue.

53. On April 26, 2018, at the end of the fiscal year,[2] Ms. Houston was the number one Minimally Invasive Therapies Group sales representatives in the entire country, measured by performance against sales quota. **Exhibit 62**.

54. In her fiscal year 2018 performance review, written in June 2018, Ms. Houston received an "Excellent" rating and exceeded all sale goals. Her sales at the end of the fiscal year were:

[2] Medtronic's fiscal year ending in 2018 ended on April 27, 2018.

Stapling:	220.89% of quota
Vessel Sealing:	174.99% of quota
Hernia:	138.29% of quota
Hardware:	101.24% of quota
New Products:	213.83% of quota
Total:	**164.96% of quota**

55. Her performance evaluation praised her "record year!" and "successful full line conversion at 6 McLeod hospitals", noting a "successful management of full transition of all hospitals to rely solely on Leanne for all issues and questions," "successfully addressed and handled surgeon resistance to change, training and adoption of new technology, price issues, coordination of manpower, communication to multiple hospitals, etc., as well as significant rolling back orders and supply challenges . . . . Strong work Leanne." **Exhibit 63**.

56. On July 7, 2018, Ms. Houston was promoted to Senior Sales Rep and substantial raise that would not only allow her more income in each paycheck, but also a greater percentage for all future sales growth and commissions.

57. At Medtronic's National Sales Meeting in 2018, Ms. Houston was named to the elite sales level "President's Club," comprised of the top 7% of sales representatives, responsible for 50% the division's total sales. *See* **Exhibit 66**.

58. Ms. Houston's June 2018 performance review also praised her for as someone who "Models Ethical Behavior," "Demonstrates courage," and "holds team accountable for ethical behavior." Ex. 63. That praise is ironic given Medtronic's retaliation, only a few months later, for her courageous attempt to it accountable for ethical behavior.

II. Leanne Houston reported dangerous defects with Medtronic's surgical staplers.

59. As noted above, from February 2018 to August 2018, there were no issues with Medtronic surgical stapler products.

60. In mid-August 2018, however, surgeons began persistently and vociferously complaining about adverse incidents with GIA80 surgical staplers causing patient injury.

61. The GIA80 stapler is a surgical stapler used to connect internal tissues in gastrointestinal procedures like organ resections. It is a simple stapler functionally identical to the Ethicon stapler McLeod surgeons had used before the "conversion" to Medtronic. It lays staggered rows of staples and simultaneously cuts and divides tissue between the two rows with a steel blade.

62. The surgeons were complaining that the staplers were causing bleeding because they were cutting past the staple line due to a manufacturing defect.

63. The defect occurred in one or more lots of GIA80 staplers due to Medtronic's willful failure to conform to cGMP.

64. Medtronic has a long history of failure to conform to cGMP in manufacturing its surgical staplers, resulting in various defects necessitating recalls. In fact, of all surgical stapler and surgical staples recalled from 2013–2019, Medtronic had 3,284,551 devices recalled, while its closest competitor recalled only 156,780 devices. Medtronic devices accounted for over 95% of the total volume of surgical stapler and surgical staples recalled.

65. In fact, Medtronic's defective staplers are a principal reason the FDA terminated the Alternative Summary Reporting Program in 2019. *See* Christina Jewett, *Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, Kaiser Family Foundation News, Mar. 7, 2010.

66. Medtronic's chronically defective staplers are also why the FDA, on October 8, 2021, reclassified tissue staplers for internal use from Class I medical devices to Class II medical devices subject to premarket notification and mandatory special controls. *See*

https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/surgical-staplers-and-staples.

67. At McLeod in late 2018, Ms. Houston was the surgeons' point-of-contact with Medtronic. Below is the list of just some of the staple line bleeds reports she received regarding the GIA80 staplers at McLeod. In total, seven separate McLeod doctors informed Relator of at least ten staple line bleeds between August 18, 2018, and October 3, 2018, with the GIA80 stapler. Ms. Houston reported each to her managers at Medtronic and completed the required internal company paperwork. These injuries resulted in additional surgeries, blood transfusions, extended stays in the ICU, sepsis, possible death, and other complications.

Date	**Surgeon**	**Procedure**	**Comment from surgeon:**
08/18/2018	Dr. Sonfield		
08/19/2018	Dr. Murrell	Appendectomy	"staple line bled X 5"
08/28/2018	Dr. Brewton		
08/29/2018	Dr. Richey	Gastro jejunostomy	"bleeding from anastomosis requiring transfusion and possible take back to operating room pending." noted patient injury. transfusion needed after patient left OR.
09/01/2018	Dr. Murrell	Gunshot patient	Voicemail to Ms. Houston at 2:00am
09/02/2018	Dr. White	Gunshot patient Lower Anterior Resection	mentions to Houston he's been having multiple issues, that "this isn't like us", meaning Medtronic.
09/14/2018	Dr. Sonfield	Ruptured diverticulitis	Showed a video of staple line bleeding to Ms. Houston
09/17/2018	Dr. Player	Appendectomy	"Pulsating arterial bleeding @ staple line." "Not isolated. Frequently with all my partners." "Return to Ethicon staplers."
09/17/2018	Dr. Sonfield	Appendectomy	"Says it is at the end. Like the knife is cutting past the staple line." Showed Ms. Houston

Date	Surgeon	Procedure	Comment from surgeon:
			video of staple line bleeding during surgery.
09/18/2018	Dr. Brewton	Resection of small bowel	"Staple line was torn from small bowel and bleeding. Had to resect small bowel three times and over sew staple line with silk. Unacceptable."
09/18/2018	Dr. White	"A colon case"	Gave Ms. Houston a video of the bleeding on Sept. 25
10/03/2018	Dr. Selander		GIA80 retrieved and sent to QA

68. Several but not all product complaint forms submitted by McLeod surgeons in August and September 2018 are attached as **Exhibit 53**. Other complaint forms were submitted. For example, on August 31, 2018, a surgeon submitted a form stating the GIA80 "fail to work on many occasions. These should not be used period." A day later, Dr. Murrell submitted a form stating, "Entire staple line bled + S -> I had to oversew all", "On gastric resection, stapler fired halfway and then would not advance or retract", "THESE STAPLERS ARE DANGEROUS", and "These staplers are dangerous to pt care. I have never seen staple line bleeding like this in 20 years."

69. On August 30, Ms. Houston notified her Medtronic sales manager, Barrett Garner, that she had received a second complaint in two days on the GIA80 stapler. Mr. Garner, seeming concerned, encouraged her to follow up. As the complaints rolled in, Ms. Houston kept Medtronic Mr. Garner up to date. Ms. Houston knew she was required and expected to be diligent in bringing the staple line bleed complaints to management's attention. Ms. Houston communicated with Mr. Garner and his boss, Medtronic Area Vice President of Sales Chuck Bland, and other Medtronic personnel. Over fifty people were aware of the bleeds. More than 31 documented text messages, videos of patients bleeding during surgery, voicemails from customers, hospital complaint forms

for each incident, and emails, were sent. Below is a list of just some of the text messages Ms. Houston sent:

Recipient	**Position**	**Dates text messages sent**
Barrett Garner	Medtronic Sales Manager	Aug. 21, Sept. 6, 18, 19, 26, 27., 28
Lou Gonzeles	Medtronic sales rep	Aug. 14, Sept. 18, 26, 30
Scott Crawford	Medtronic sales rep	Sept. 18, Oct. 9, 16
Andrew McNeil	Nurse at McLeod	Sept. 18
Matt Mollison	Medtronic sales rep	Sept. 19, 20, 27
Marc Kochamba	Medtronic sales rep	Sept. 21
Andrea Margolis	Medtronic sales rep	Sept. 25, Oct. 5
Dr. Christine Mauro	Medtronic medical director at North Haven, CT, manufacturing facility	Sept. 18, 25
John James	Medtronic stapling manager	Sept. 26
Tim Munnerlyn	Medtronic sales rep	Sept. 28
Andy Heeps	Medtronic global quality complaint manager	Oct. 1, 3
Chuck Bland	Medtronic group AVP	Sept. 10, 11, 27, 28

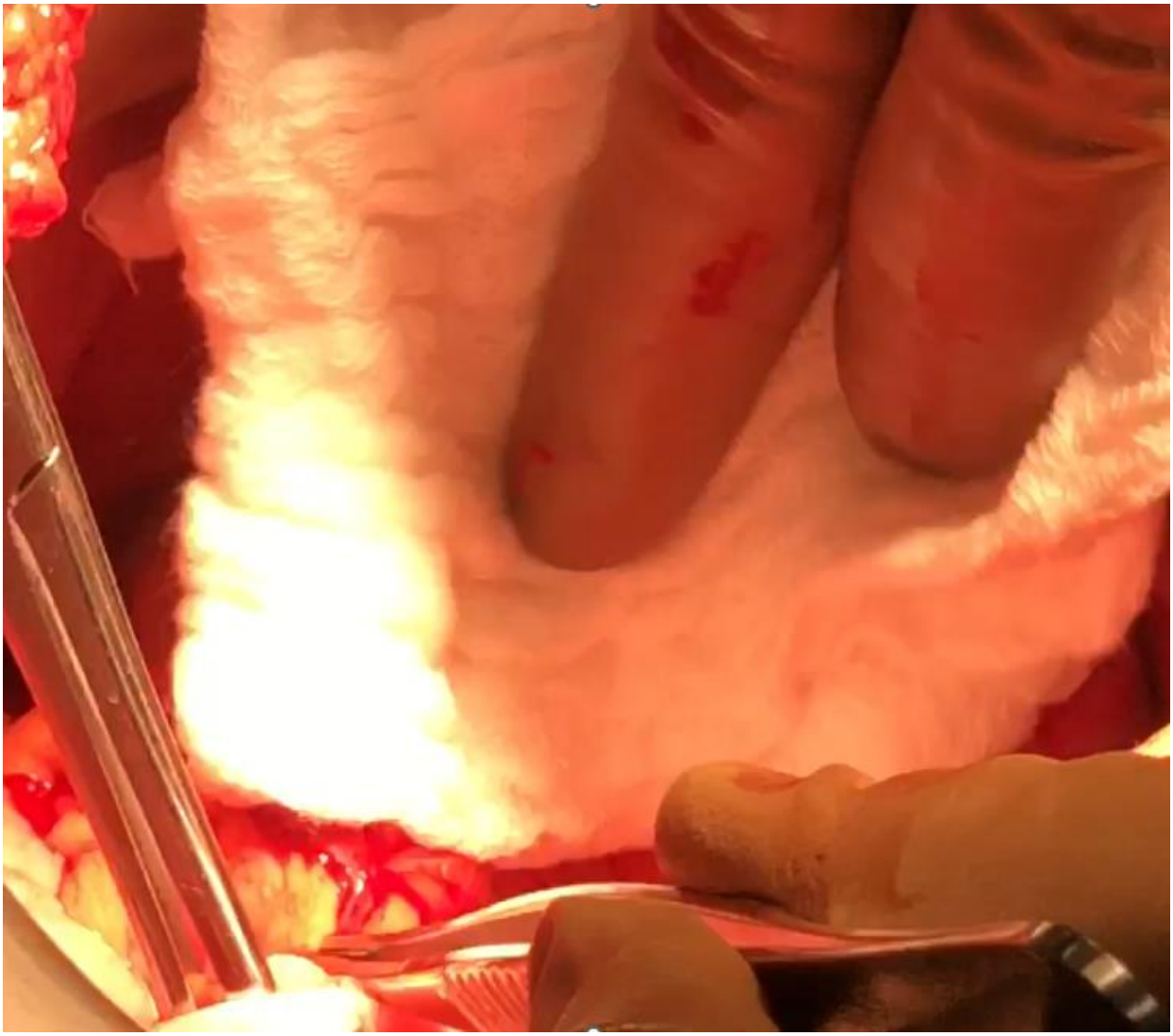
70. Ms. Houston asked Mr. Garner if they could remove a GIA stapler from the shelf and have it tested. His response was a harsh "no", that would be "instigating a recall at her level." Ms. Houston then asked if he wanted her "to stand there and watch the patient bleed?" Mr. Garner replied "yes, and then send the product in to be tested."

71. On September 18, 2018, Angela Putnam, McLeod's Value Analysis Coordinator, sent an email to Ms. Houston and Mr. Garner, stating, "The attached items have presented with numerous complaints, from various surgeons, in which you have been notified and asked to

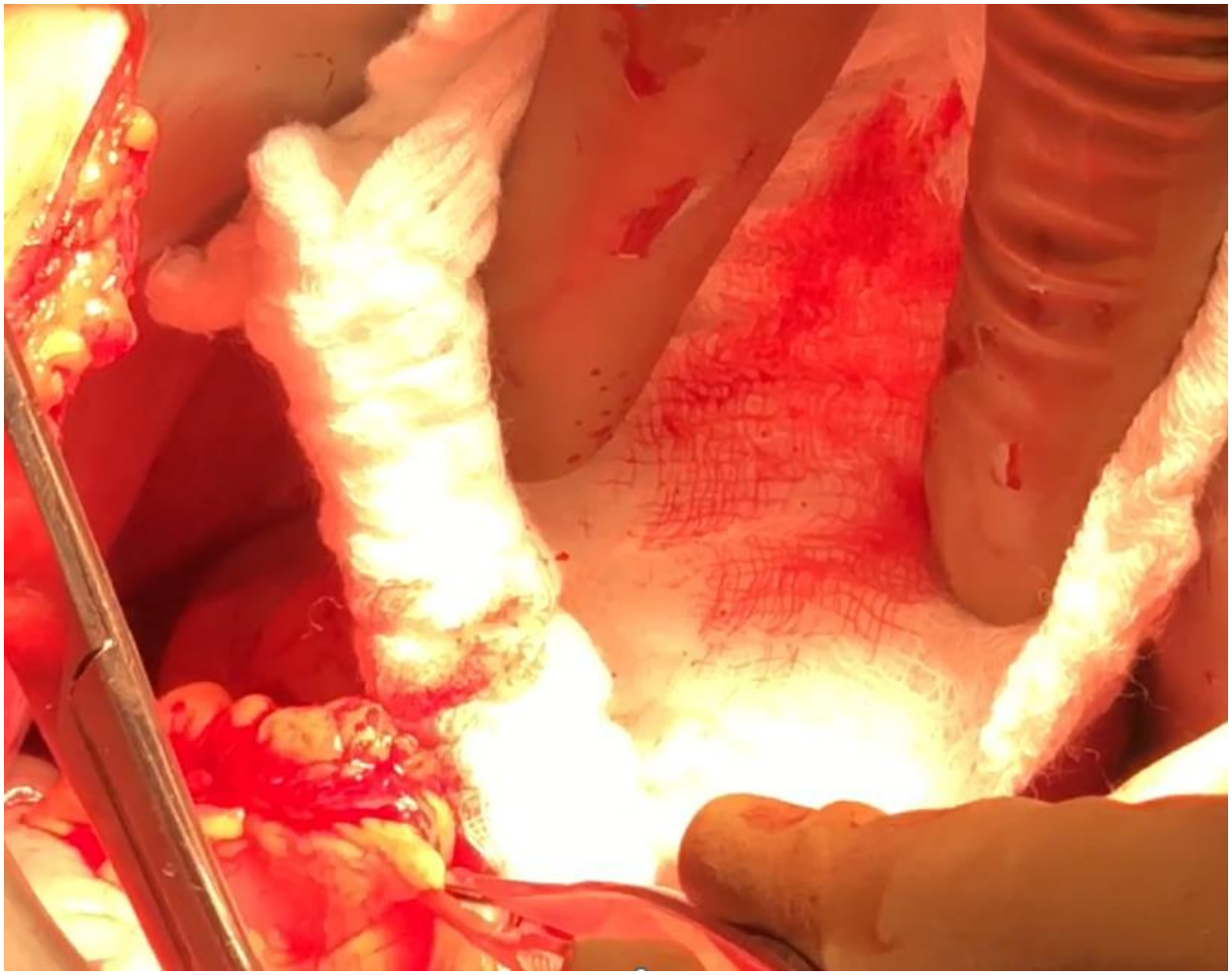
investigate. Given the severity of these concerns, what are our next steps and best options to ensure safe patient care?" **Exhibit 54**.

72. The next day, on September 19, 2018, a transcribed meeting was held about concerns with Medtronic products, including the GIA80. It was led by Dr. Michael Rose (VP at McLeod who was considered the "champion" and leader of the conversion on the McLeod side—a physician but an anesthesiologist serving as a full-time hospital executive, not a surgeon). Ms. Houston and Mr. Garner attended. At the transcribed meeting, Andrew McNeil (a nurse who had been on the "VIP" trip to New Haven), reported, "the surgeons feel like we are compromising quality of care that we are providing to these patients. Now they are seeing bleeding around the staple lines with the previous product they were not. . . . The surgeons are having to sew over the staple line." Mr. Garner promised an action plan.

73. Thereafter, on September 25, 2018, Dr. White, a surgeon considered an ally of the Medtronic "conversion," provided Ms. Houston a copy of a video of a bleeding event that occurred in a colon procedure a week earlier to demand that Medtronic to do something about the defective stablers. The video is attached as **Exhibit 70**. Below are two still frame images from the video.



The above image shows the surgeon placing a clean white gauze next to the staple line in the patient's colon, within the open abdominal cavity. The below image shows the same gauze covered in blood less than ten seconds later. The gauze did not touch the staple line in the colon; as can be seen in the video, the blood squirted from the colon with each heartbeat and sprayed the gauze and the surgeon's fingers. This is a serious and injurious surgical complication requiring immediate corrective action. A patient in a different procedure less than three weeks before this required a blood transfusion because of such bleeding.



74. On September 27, 2018, another meeting was held with Dr. Rose. Mr. Garner, Mr. Bland, and Ms. Houston attended. Dr. Rose said he had been "a tad bit anxious about things lately." Mr. Bland suggested switching McLeod surgeons to a different stapler. Ms. Houston, however, would not adopt the party line of "user error," given that the surgeons had used the staplers without issue for months, and she would not discount the obvious possibility of a defective lot of staplers.

75. On October 1, 2018, another hospital C-suite meeting with Dr. Rose was held to discuss complaints about the staplers. Mr. Bland attended with Ms. Houston. McLeod asked to switch back to the Johnson & Johnson stapler they had used before switching to the GIA80. Mr. Bland countered by offering instead to switch from the GIA80 to a different, more expensive

Medtronic stapler that would be offered at the same price. Mr. Bland told Dr. Rose to keep in mind it isn't about this one conversion, but also about planned suture conversion and all the other Medtronic divisions to follow, and to "think of the rebates and savings to come. We need to get this situation under control." Ms. Houston again would not adopt the party line of "user error," given that the surgeons had used the staplers without issue for months, and she would not discount the obvious possibility of a defective lot of staplers.

76. On October 7, 2018, Mr. Bland yelled at Ms. Houston in front of other Medtronic employees, stating that he didn't ever want to hear her discuss the possibility of a lot number issue with the GIA80 stapler again, that she was putting the "conversion" at risk.

77. On October 9, 2018, Mr. Garner provided the promised action plan—instruct surgeons to switch from the GIA80 to other staplers made by Medtronic, particularly the more expensive "TriStaple" stapler used in thoracic procedures. **Exhibit 55**.

78. The defect in the GIA80 staplers at McLeod was caused by Medtronic's willful failure to conform with cGMP as required by law. Some of the victims of the above-reported procedures using Medtronic's defective staplers were Medicare (e.g., the ruptured diverticulitis case) or Medicaid (e.g., the gunshot case) beneficiaries. All Medtronic staplers in the period August 19 to October 3 were defective, including those used in procedures billed to Government Health Insurance Programs in that period.

79. That is precisely why Mr. Garner told McLeod to cease using the GIA80 and to instead use different models of surgical staplers. He knew the GIA80 was defective.

III. Medtronic concealed the dangerous defects and continued to injure patients.

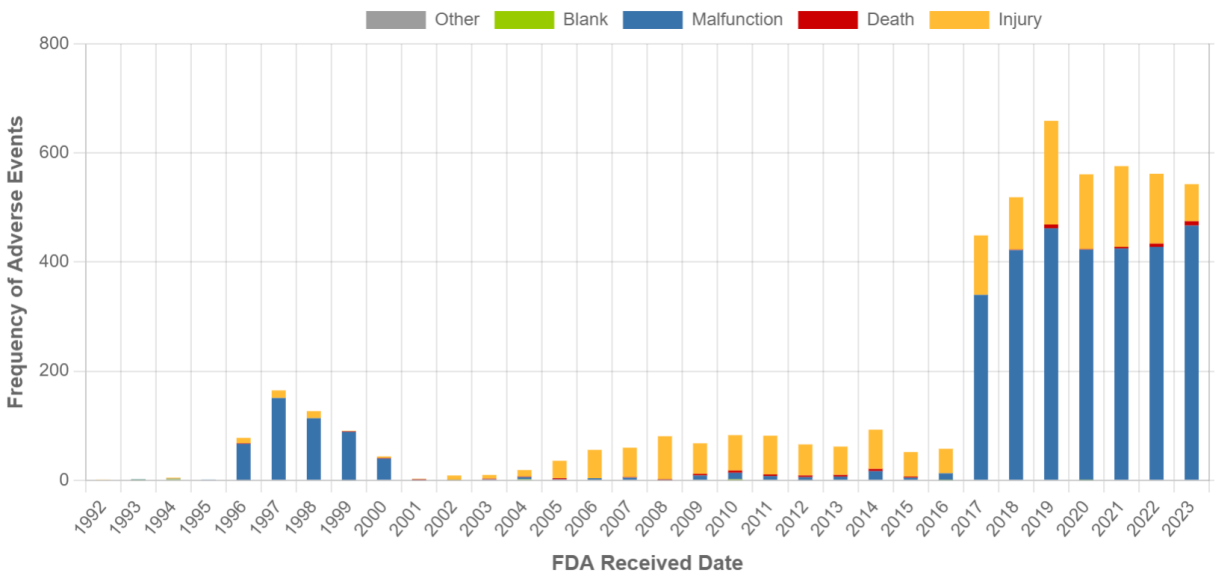
80. Medtronic was required to submit MDRs on adverse incidents resulting in patient injury within five business days.

81. But an investigation of Medtronic's own reports to the FDA on adverse events with its stapler products at McLeod hospitals from 2017–2019 shows that Medtronic did not investigate or report all injuries correctly. **Exhibit 44**.

82. In 2001, Medtronic applied for exemption from the typical MDR reporting program under the Alternative Summary Reporting (ASR) Program. The ASR program was in place until 2019 and was intended to provide a simpler way for manufacturers to report well known malfunctions that did not affect the patient. The FDA ended this program in 2019 after a Kaiser Health News investigation found that the adverse events reporting surgical stapler device failures causing patient harm submitted the ASR program had hidden the data, preventing physicians from learning the true failure rates of surgical staplers.

83. Medtronic, in particular, often illicitly hid adverse incidents resulting in patient injury or risk of patient injury in ASRs. It also hid them by reporting products under obscure subsidiary company names like "US Surgical Puerto Rico."

84. Medtronic, however, ceased reporting stapler-related reports through the ASR program after July 2017. The resulting spike in MDR adverse incident reports for Medtronic GIA staplers is obvious:



85. Regarding issues in 2018 and later, the point is that Medtronic was aware its staplers were adulterated as defined by FDA regulations and it had a history of attempting to conceal mandatory adverse incident reports to avoid costly recalls of its adulterated staplers.

86. As noted above, 95% all surgical stapler and surgical staples recalled from 2013–2019 were Medtronic products.

87. In its first 2018 stapler recall, Medtronic revealed that "five people were injured related to missing components that could affect staple alignment" involving the "Endo Gia Articulating Reloads with Tri Staple Technology." This recall involved 171,271 units and drew significant media attention. **Exhibit 48**. Medtronic later recalled 3,113,280 units of the Endo GIA Stapler in the Spring of 2019 for failure to fully insert staples.

88. Three months after Medtronic's first recall caused by five reported injuries (Medtronic recall May 2018 FA868), at least ten staple line bleeds, including injuries, occurred at McLeod Hospital. These bleeds involved a different stapler that was not included in the over 3 million devices recalled in 2018 and 2019 by Medtronic.

89. The staple line bleeds were caused by a manufacturing problem which should have led to a recall. The problem was not caused by user error, as the McLeod surgeons had been successfully using the device for months before the rash of complaints beginning shortly the six-month business review on August 16, 2018 (at which there were no complaints regarding the GIA80 stapler).

90. Medtronic avoided a recall in part by incorrectly reporting the adverse incidents to the FDA. For example, the MDR for Dr. Sonfield's issue during a procedure for perforated diverticulitis states:

US SURGICAL PUERTO RICO GIA; STAPLE, IMPLANTABLE Back to Search Results

Model Number GIA8038S
Device Problem Failure to Form Staple (2579)
Patient Problem No Code Available (3191)
Event Date 09/15/2018
Event Type Injury
Manufacturer Narrative
(b)(4) (ovewsew) if information is provided in the future, a supplemental report will be issued.

Event Description
According to the reporter, when stapling small bowel during a laparoscopic colon perforated diverticulitis small bowel, there was an incomplete staple line.The surgeon said that the stapler cut beyond the staples and was bleeding.It was stated that the bleeding was on the third reload or firing.They had to oversew to fix the bleeding staple line.

Brand Name	GIA
Type of Device	STAPLE, IMPLANTABLE
Manufacturer *(Section D)*	US SURGICAL PUERTO RICO 201 Sabanetas Industrial Park Ponce PR 00716 4401
Manufacturer *(Section G)*	US SURGICAL PUERTO RICO 201 Sabanetas Industrial Park Ponce PR 00716 4401
Manufacturer Contact	Lisa Hernandez 60 Middletown Ave. North Haven, CT 06473 2034925563

The narrative reflects what Dr. Sonfield reported, that the stapler cuts beyond the staple line. But Medtronic reported it incorrectly. It reported the problem coded as "Failure to form staple (2579)"

which the FDA defines as "Problem associated with the device failing to connect tissue with a stapling device due to the staples not forming correctly." It is a problem with the staples rather than the stapler and Medtronic therefore reported this as a problem with the staples and not the stapler.

91. Medtronic also avoided a recall by demanding Ms. Houston stop raising the issue. As noted above, when Ms. Houston asked to remove a stapler from McLeod's inventory for testing, her manager said "no" harshly. When she asked if he wanted her "to stand there and watch the patient bleed?", he replied "yes."

92. Also as noted above, Ms. Houston brought complaints about the GIA to Mr. Garner's supervisor, Area Vice President of Sales Chuck Bland, and to the Medical Director of the Company, to the Global Quality Director, to the Stapling Product Manager, to Human Resources and to the Legal Department of Medtronic, among others. She did so because the stapler's unreliability put patient safety at risk.

93. In response, Mr. Bland angrily yelled at her on October 7, 2018, in front of other Medtronic employees, stating that he didn't ever want to hear her discuss the possibility of a lot number issue with the GIA80 stapler again, that she was putting the "conversion" at risk, meaning Medtronic's sales campaign intended to cause McLeod to cease to use competitor products and to use Medtronic staplers exclusively.

94. Medtronic "converts" hospital networks to use its inferior products exclusively by aggressive "conversion" marketing campaigns aimed at non-physician decisionmakers at the hospital. To persuade those decisionmakers, Medtronic promises to undercut competitor prices significantly. Doing so despite the expensive marketing campaign requires cutting costs somewhere, which is why Medtronic does not follow cGMP in manufacturing products like

staplers, which explains why Medtronic staplers comprise 95% of all stapler recalls and why Medtronic resorts to fraudulent practices to avoid even more stapler recalls.

IV. Medtronic retaliates against Ms. Houston.

95. All Ms. Houston's concerns about the GIA80 stapler were made prior to Medtronic taking adverse action against Relator as an employee, and in fact were the impetus for Medtronic's retaliatory actions against Relator.

96. Relator was a star sales representative until the very last months of her employment. Her sales numbers were among the best in the country. She had recently secured a $2.2 million dollar account that opened the door to even more expansion in her eastern South Carolina territory. She had just been awarded President's Club, a promotion, a substantial raise, and had a spotless review from her supervisor. Her customers loved and trusted her. Her peers respected her. She had every intention to spend the rest of her career at Medtronic, a company she had loved and long admired.

97. Ms. Houston's July 7, 2018, promotion to Senior Sales Rep provided both a substantial raise and a greater percentage for all future sales growth and commissions. Her trending sales numbers were $700,000 over quota for fiscal year 2019 (beginning at the end of April 2018). This trend was forecasted to continue for years to come. McLeod was a growing hospital system. Because of her successes in securing and implementing the McLeod conversion, she would be able to secure her financial retirement in ten years.

98. But in her last months of employment, Ms. Houston raised a product safety concern regarding what appeared to be a bad batch of surgical staplers. Her supervisors responded by inventing a litany of false performance critiques and outright lies attempting to tie her to the staple line bleeds and summarily fired her.

99. On October 17, 2018, Mr. Garner and Mr. Bland told her she was not working hard enough and told her that she was required to "sign in" by 7am every day—no other sales representatives were required to do that.

100. On October 19, 2018, Mr. Garner sent a letter to Mr. Bland and to human resources criticizing Ms. Houston's job performance including one lie—that a surgeon had asked her leave the room during a procedure at McLeod—that was so outrageous and provably false that Mr. Garner changed it five times before withdrawing it entirely on November 14, 2018.

101. On October 22, 2018, Medtronic's human resources department began proceedings that resulted in a decision to terminate Ms. Houston for "incompetence."

102. Ms. Houston did not transform from Medtronic's top-performing sales representative to an incompetent who does not work hard enough, who does not show up to work on time, and who is kicked out of the room by clients, in a few weeks that just happened to be immediately after she refused to deny that Medtronic staplers might have the manufacturing issue reported by numerous surgeons she was working with. These actions were retaliation for Ms. Houston's whistleblowing—specifically, her refusal, in meetings with Mr. Bland and Dr. Rose, to deny that there was an issue with the staplers and to agree that the adverse events were due to surgeons' "user error."

103. Relator took her hard-earned President's Club Trip on November 2–4, 2018, two weeks after being accused by Mr. Garner of "incompetence" in the stapling area in which Relator was whistleblowing. While there, she was praised by Jeff Kozial, VP of Medtronic, as he shared with the room full of winners and Corporate VIPs, how Ms. Houston had trained him over 20 years ago when he first started his career and how much he respected her. Ms. Houston, after introducing herself and giving a small background of her time away from sales to raise her children after a

difficult divorce, described how Covidien and Medtronic had welcomed her back with open arms, and how after five years she made it back to the top of her game at age 53. She was told numerous times how inspiring her story was.

104. On December 10, 2018, Ms. Houston was informed that she would be terminated for "incompetence," *only seven months after she was the number one sales representative in the entire country* and *only three months after she reported concerns about the safety of Medtronic surgical staplers at McLeod*.

105. As a result, she found herself in the unenviable position of an unemployed woman in her 50s with highly specialized skills, a non-compete agreement, a compromised personnel file, and a black mark on the brightest spot on her resume.

106. Ms. Houston told her children on Christmas Day that she would soon be losing her job and her only source of income. In January 2019, as her termination was being processed, *she was still the highest-performing sales representative in Mr. Garner's region*, despite having been effectively suspended since October 2018. *See* **Exhibit 68**.

V. After Medtronic terminates Ms. Houston, the defective staplers continue to injure patients and McLeod is forced to buy its way out of its contract with Medtronic so that it can return to using Johnson & Johnson products that do not injure patients.

107. After Medtronic terminated Ms. Houston, its defective surgical staplers continued to injure patients at McLeod. For example, on February 1, 2019, Dr. Murrell complained "every staple line bled and was oversewn" with sutures to correct. On February 11, 2019, "During a Small Bowel resection Dr. Selander had to oversew the staple line due to bleeding at the site."

108. McLeod was forced to pay for an early termination of its "conversion" agreement with Medtronic and to return (at a premium) to its former relationship with Johnson & Johnson, which sells surgical staplers manufactured in accordance with cGMP that are rarely recalled and do not injure patients. The "conversion" agreement was officially terminated on October 4, 2019.

FOR A FIRST CAUSE OF ACTION

Violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A)–(B)

109. Each of the paragraphs above is re-alleged and incorporated here verbatim.

110. At all times relevant to this action, Medtronic was required to abide by the adulteration requirements of the FDCA and related regulations, and by adverse event reporting requirements.

111. The product defects described above made the GIA80 staplers ineligible for marketing and sale and required disclosure to the FDA and remediation to protect consumers.

112. Instead, Medtronic knowingly concealed the manufacturing defect and the risk to patients and placed an adulterated and worthless product into the stream of commerce, knowing it would be used in procedures billed to the federal programs identified above and that it would render those services worthless.

113. By virtue of the conduct described above, Medtronic knowingly or caused to be presented, false or fraudulent claims for payment to federal healthcare programs.

114. The United States, unaware of the false or fraudulent nature of the claims that Medtronic caused, paid for claims that otherwise would not have been allowed.

115. The surgical procedures in which the defective staplers were used were billed as procedures, and the staplers were not directly billed to the Government. However, Medtronic caused those procedures to be worthless by providing surgical staplers that caused patient injury, including the need for blood transfusions and further corrective procedures.

116. The services were worthless because, in the face of full disclosure of all relevant facts, neither the Government nor anyone else would buy the service at any price. No one would purchase a colon resection, for example, from a provider who disclosed that he would use defective tissue staplers causing major bleeding issues and requiring follow up surgery to correct. Everyone

would instead purchase the needed service from someone using non-defective surgical tools. The market value of the defective service is zero because no fully informed buyer would agree to pay for it. To get anyone to agree to pay for it requires fraud.

117. Further, "It is not necessary to show that the services were completely lacking; rather, it is also sufficient to show that 'patients were not provided the quality of care' which meets the statutory standard." *United States v. Villaspring Health Care Ctr., Inc.*, No. CIV.A. 3:11-43-DCR, 2011 WL 6337455, at *5 (E.D. Ky. Dec. 19, 2011); *see also United States ex rel. Scharber v. Golden Gate Nat'l Senior Care LLC*, 135 F. Supp. 3d 944 (D. Minn. 2015); *United States ex rel. Academy Health Ctr., Inc. v. Hyperion Found., Inc.*, No. 10-552, 2014 WL 3385189 (S.D. Miss. July 9, 2014); *United States v. NHC Healthcare Corp.*, 115 F. Supp. 2d 1149 (W.D. Mo. 2000); *United States v. Am. Health Found. Inc.*, No. CV 22-02344, 2023 WL 2743563, at *12 (E.D. Pa. Mar. 31, 2023). "A bundle of services can, on average, be worthless even if some of them were administered properly." *United States v. Am. Health Found. Inc.*, No. CV 22-02344, 2023 WL 2743563, at *13 (E.D. Pa. Mar. 31, 2023).

118. By reason of these payments for services Medtronic rendered worthless, the United States has been damaged in a substantial amount.

119. Defendant's conduct is a violation of 31 U.S.C. § 3729(a)(1)(A) & (B).

FOR A SECOND CAUSE OF ACTION

Retaliation in violation of 31 U.S.C. § 3730(h)

120. Each of the paragraphs above is re-alleged and incorporated here verbatim.

121. Medtronic retaliated by harassing Relator Leanne Houston and taking adverse employment actions against her, preventing her from properly carrying out job responsibilities as a result of lawful acts done in furtherance of this action, including reporting violations of the FDCA

to Medtronic management and refusing to engage in Medtronic's scheme to promote unreliable and worthless medical equipment.

122. As a direct and proximate result of this unlawful and discriminatory retaliation, Relator Leanne Houston has suffered emotional pain and mental anguish, together with serious economic hardship, including increased medical expenses, lost wages, and special damages associated with Relator Houston's efforts to obtain alternative employment in an amount to be proven at trial.

PRAYER

WHEREFORE, Plaintiff/Relator prays for judgment against Defendant, and that the Relator and the United States be granted the relief demanded below:

For Count 1:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims and frauds alleged within this Amended Complaint, as provided under the False Claims Act, 31 U.S.C. §§ 3729 et seq.;

(b) That civil penalties be imposed for each false claim that Defendant presented or caused to be presented to the United States or its agencies;

(c) That pre-judgment and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the False Claims Act;

For Count 2:

(a) Judgment in favor of Plaintiff and against Defendant in an amount which is fair, just, and reasonable, and for actual, compensatory, consequential, special, and punitive damages;

(b) Prejudgment interest and costs as may be allowed by law;

(c) Judgment in favor of the Plaintiff and against Defendant with two times back pay and associated benefits Plaintiff would have earned, interest on back pay,

reinstatement with appropriate seniority status, and all lost or diminished benefits to be determined by the trier of fact;

(d) Judgment in favor of the Plaintiff and against Defendant for front pay and any other work benefits lost in an amount to be determined by the trier of fact;

(e) Judgment in favor of the Plaintiff and against Defendant in an amount sufficient to compensate Plaintiff for all special damages suffered, including attorney's fees, pain and suffering, embarrassment, humiliation, shock, and emotional distress; and,

(f) Judgment in favor of the Plaintiff and against Defendant for punitive damages sufficient to impress upon Defendants the seriousness of their conduct; and

For All Counts:

(a) That the Court award such other and further relief as it deems just, fair, and proper under the circumstances.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury on all issues so triable.

[signature block follows]

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